Craig P. Tanio, M.D



Ben Steffen EXECUTIVE DIRECTOR

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January 23, 2017

By E-Mail and USPS

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Re: Motion to Strike Recommended Decision
Baltimore Upper Shore Cardiac Surgery Review
Anne Arundel Medical Center (Docket No. 15-02-2360)
University of Maryland Baltimore Washington Medical Center
(Docket No. 15-02-2361)

Dear Counsel and Dr. Chan:

On January 19, 2016, the University of Maryland Baltimore Washington Medical Center ("BWMC") filed a Motion to Strike the Recommended Decision in the Baltimore Upper Shore Cardiac Surgery Review. Having reviewed the motion, I have determined that it is not necessary that I receive responses to that motion from the other parties in this review before ruling on the motion. While I deny BWMC's motion, I have concluded that it is not appropriate for my December 30, 2016 Recommended Decision to be considered by the Maryland Health Care Commission at its January 26, 2017 meeting. I believe the parties should receive and have an

opportunity to comment on certain data, including: the 2020 population projections that are included in the record but were not easily identifiable because the data file was not accompanied by the record layout/key; and a Virginia Health Information data set, which, while not substantively altering my analysis, was regrettably omitted. Both the record layout and the information on the small number of Virginia hospital discharges originating in the applicant hospitals' service area should have been included with my provision of the zip code area population data sets.

I will address each point made by BWMC in its motion.

2020 Nielsen Population Projections

BWMC is correct that my Recommended Decision makes reference to the 2020 Nielsen population projections; however, it is incorrect in its statement that the 2020 Nielsen population projections were not included in the data entered into the record on December 30, 2016. The record includes population estimates or projections for 2014, 2015, 2019, 2020, and 2024. The file labeled "DEMZIP 1886936001.xlsx" ("DEMZIP file"), includes population estimates from Nielsen for 2015 as well as population projections for 2020 and 2024. The layout for this file is similar to that for the 2014 and 2019 projections (labeled "2014, 19 Pop by zip & Age Cohort for Nielsen.xlsx"), in that it contains a current year ("C") in the age cohort labels and a five-year projection for 2019, with "F" included in the age cohort labels. The DEMZIP file includes letter "C" in the age cohort labels for the Nielsen 2015 current year population estimates, the letter "F" in the age cohort labels for the 2020 population (five-year) projections, and the letter "P" in the age cohort labels for the 2024 projections. Unfortunately, unlike the 2014 and 2019 file, the 2015-2020-2024 DEMZIP file did not include a record layout explaining the years of the data included. Attached is the record layout key that shows the layout for "DEMZIP_1886936001.xlsx" file that was entered into the record and provided to the parties on December 30, 2016.

Entry of Data from Discharge Databases into the Record; Sources in the Recommended Decision's Analysis of Minimum Volume

BWMC is incorrect when it states that I "did not enter data from either [the Health Services Cost Review Commission's ("HSCRC") Discharge Database or the District of Columbia Discharge Database] into the record." (BWMC motion, p. 3). In my October 5, 2016 letter to the applicants sent by email (document labeled "Tanio_Request for Info and Notice_Balt Upper Shore Cardiac Surgery_100516.pdf"), I gave the following notice:

Notice of use of HSCRC Discharge Database and District of Columbia Discharge Database in this review.

I intend to use information beginning with Calendar Year 2009 to the most recent quarter of information available from the HSCRC Discharge Database and from the District of Columbia Database in this review. **If either applicant or any**

party in this review does not have access to the HSCRC database, I recommend that you gain access to patient-level de-identified data by making the required application(s) found on HSCRC's website at: http://www.hscrc.maryland.gov/hsp-data-request.cfm. If you do not have access to the District of Columbia Discharge Database for this time period, you should obtain access by following the application procedure at:

http://mhcc.maryland.gov/mhcc/pages/apcd/apcd_data_release/apcd_data_release_dcdischarge.aspx.

(Docket Item #74GF, p. 4)(emphasis in original).

As noted in the source note for Table 5, my forecasting model replicates that found in COMAR 10.24.17.10 at the hospital MSGA service area level, The age-adjusted use rate trend for the zip code areas constituting the AAMC and BWMC 85% relevance MSGA service areas for the five-year period of CY 2009 through CY 2014 is projected forward, using the service area population projections, to produce the 2015 through 2020 projections. I used only the HSCRC Discharge Database to determine the zip code areas in the 85% relevance MSGA service areas of the applicant hospitals because only that database is necessary to determine the list of zip code areas in a service area definition of this type. However, I also used the D.C. Discharge Database and Virginia Health Information ("VHI") to determine the case count for the service area zip code areas.

I did use information from the HSCRC, the District of Columbia ("D.C."), and the VHI discharge databases to develop the projections of total cardiac surgery case volume for 2015 to 2020. Regrettably, I omitted identification of the D.C. Discharge Data Base as a source reference for Table 5 on page 28 of the Recommended Decision. I also did not note VHI as a source for a small number of cases, 13 cases overall, for a few Maryland zip code areas that were also incorporated in this projection. All 13 of these Virginia cases originated in zip codes in the service area of Anne Arundel Medical Center ("AAMC"), and one of these cases came from a zip code that is also included in the BWMC service area. The VHI data set is attached. The case counts for Maryland residents discharged from Virginia hospitals for zip code areas included in the AAMC and/or BWMC service areas in 2014 were as follows:

Zip Code	Cases	Zip Code	Cases
20706:	2	20772:	3
20715:	1	20774:	3
20716:	1	21012:	1
20720:	1	21122:	1

² Constituting 1.8% of the total 708 CY 2014 cases in the AAMC 85% relevance MSGA service area.

¹ Out of a total of over 800 unduplicated cases.

³ Constituting 0.3% of the total 376 CY 2014 cases in the BWMC 85% relevance MSGA service area.

CY 2020 Use Rates

BWMC is incorrect in its statement that the "State Health Plan requires the parties to rely upon the most recent utilization projections." (BWMC motion, p. 3). The minimum volume standard in the Cardiac Surgery Chapter, at COMAR 10.24.07.05A(1)(d), provides that

[t]he applicant's demonstration of compliance with the Minimum Volume and Impact standards of this chapter shall address the most recent published utilization projections of cardiac surgery cases in Regulation .10 for the health planning region in which the applicant hospital is located and any other health planning regions from which it projects drawing 20 percent or more of its patients. The applicant shall demonstrate that its volume projections and impact analysis are consistent with the projection in Regulation .10 or, alternatively, demonstrate why the methods and assumptions employed in the Regulation .10 projections are not reasonable as a basis for forecasting case volume.

Notably, an applicant is not required to "rely upon" the regional projections but must only address the projections in their demonstration of compliance with the Minimum Volume and Impact standards and account for the regional projections in their demonstration of compliance with the Need standard.

It is obvious that the regional case volume projections cannot be relied upon to demonstrate full compliance by an applicant hospital with the Minimum Volume, Need, or Impact standards, given that the regional projections simply provide case volume projections for large multi-county regions. In contrast, the Minimum Volume and Impact standards require analyses of the volume that can be attained at a specific hospital level and the impact that new cardiac surgery programs are likely to have at a specific hospital level. BWMC showed that it understood this distinction in its CON application, where it addressed the regional projection in its service area-level analysis of likely volume and likely impact by adopting the assumption in the regional projections that cardiac surgery use rates are trending downward.

BWMC is incorrectly conflating the service area-level and zip code area-level analysis of volume required by COMAR 10.24.17.05A(6), the Need standard, with the published regional case volume projections. These are two completely different and separate types of case forecasts, a regional forecast that includes an indication of how cardiac surgery cases are assumed to be trending and a hospital service area-level forecast, undertaken using zip code areas. Subsection .05A(6) of the Need standard requires an applicant to "account for the utilization trends in the most recent regional projections of cardiac surgery cases," which, as noted, is a downward utilization trend. Each applicant accounted for this downward trend in its forecast of case volume, as did I in employing a different service area definition and more conservative market share assumptions in order to test the service area-level and zip code area-level forecast put forth by the applicants.

Zip Codes in AAMC's 85% Relevance MSGA Service Area for CY 2014

BWMC correctly notes that my identification⁴ of AAMC's CY 2014 85% relevance MSGA service area of AAMC as including only 39 zip code areas was in error. I actually used 41 zip code areas for AAMC's 85% relevance service area, but mistakenly stated 39 instead of the correct 41 zip code areas. Thus, 41 zip code areas were the basis for AAMC's service area case volume projections in Table 5 and there is no missing or undisclosed data other than the 13 Virginia hospital cases.

Supposed Reliance on an Alternative Method to Analyze Minimum Volume

BWMC is incorrect in its statement that I relied upon a new, alternative model to analyze minimum volume. Instead, I described the applicants' service area-level forecasting models and market share assumptions and found that each applicant conformed with the guidance of the Cardiac Surgery Chapter, found at COMAR 10.24.17.05A(1) and A(6). I did not question the elements of the models used by the applicants but questioned the reasonableness of the assumptions used by each applicant in constructing its model. I also developed a forecast model which, like the applicants' models, conforms with the State Health Plan guidance on forecasting case volume. However, I used more conservative assumptions based on the experience of the Maryland cardiac surgery hospitals that are most similar to the applicants. BWMC mischaracterizes the guidance of the Cardiac Surgery Chapter, which it incorrectly describes as containing a method for forecasting case volume. Instead, the regulatory guidance in forecasting minimum volume is limited to describing: the geographic base that must be used - a defined cardiac surgery service area; and the level of geography that must be used - zip code areas. My analysis using MSGA service areas fully conforms with this guidance, as noted in my source note for Table 5.

Further Proceedings

I anticipate that the parties will be able to file comments by 4:30 p.m. on February 1, 2017 regarding: the 13 Virginia cardiac surgery cases from the VHI data set that are hereby entered into the record of this review; and the previously furnished 2020 population projections in light of the attached record layout now entered in the record of this review. Any party that requires additional time should so advise me by 4:30 p.m. on Tuesday, January 24, 2017, setting forth details of why additional time is required. Other parties will have five business days to respond to the comments regarding the data. I believe that it is likely that I will issue a revised Recommended Decision that considers the comments and makes corrections or clarifications to the December 30, 2016 Recommended Decision that I believe are appropriate.

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⁴ Recommended Decision, p. 29.

I remind the parties that the ex parte prohibitions in the Administrative Procedure Act, Maryland Code Ann., State Gov't §10-219, apply to this proceeding until the Commission issues a final decision.

Sincerely,

Craig Tanio, M.D. Chair/Reviewer

Enclosures (by email)

cc: Leana S. Wen, M.D., Baltimore City Health Commissioner Gregory Wm. Branch, M.D., Baltimore County Health Officer Leland Spencer, M.D., Caroline and Kent County Health Officer Edwin F. Singer, L.E.H.S., Carroll County Health Officer Stephanie Garrity, M.S., Cecil County Health Officer Susan C. Kelly, R.S., Harford County Health Officer Maura J. Rossman, M.D., Howard County Health Officer Joseph A. Ciotola, M.D., Queen Anne's County Health Officer Fredia Wadley, M.D., Talbot County Health Officer Steven R. Schuh, Executive, Anne Arundel County Paul Parker Kevin McDonald Suellen Wideman, AAG Siobhan Madison, AAG